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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,053	05/28/2007	Mordechai Frisch	P-6166-US	7967
49443 7590 10/27/2011 Pearl Cohen Zedek Latzer, LLP 1500 Broadway 12th Floor New York, NY 10036				
EXAMINER SMITH, PHILIP ROBERT				
ART UNIT		PAPER NUMBER		
3779				
NOTIFICATION DATE		DELIVERY MODE		
10/27/2011		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

USPTO@pczlaw.com
Arch-USPTO@pczlaw.com

Office Action Summary

Application No.

10/585,053

Applicant(s)

FRISCH ET AL.

Examiner

PHILIP R. SMITH

Art Unit

3779

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 September 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1,3,4,6,9,13,31-34,37 and 40-48 is/are pending in the application.
- 5a) Of the above claim(s) 9 and 45 is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1,3,4,6,13,31-34,37,40-44 and 46-48 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Election Requirement

[01] The specification refers to multiple types of fastener. As noted in [0030] of the Publication, "[h]eavy part 30 and light part 12 may be attached or releasably and/or detachably held together by a fastener 202 such as for example glue, fuses, wires, magnets."

- See [0031]: "fastener 202 may be or may include a wire or filament such as for example a fuse or heat sensitive or degradable filament... heat may be applied to or a current may be passed through fastener 202 such as for example a heat sensitive filament or fuse, and heat sensitive filament or fuse may melt or degrade."
- See [0032]: "fastener 202 may be for example one or more magnets, magnetized materials or materials that are responsive to an electromagnetic force."
- See [0033]: "fastener 202 may be a degradable filament or glue that may degrade... Such degradation may be precipitated by for example exposure to body temperatures, exposure to certain liquids, pH levels or other elements or conditions as may be present in a body lumen."

[02] These three species of fastener identified in paragraphs [0031], [0032] and [0033] of the Publication are mutually exclusive and require different search queries. They are composed of divergent materials and are made to detach with different methods. They represent divergent searches which constitute a serious burden to examination. For this reason, the requirement is made final.

[03] Applicant contends that a heat-sensitive element is also degradable, and that the species of [0031] and [0033] are therefore not mutually exclusive. In the general sense, melting may be considered a form of degradation. Paragraph [01c] of the outstanding Office action does indeed refer to "a

degradable filament." But this is a truncated reference to the embodiment of [0033], whereas paragraph [01a] of the outstanding Office action refers to the embodiment of [0031]. As noted in paragraph [08] of the Office action of 6/6/11, Applicant elected the "degradable filament or glue" which is supported in [0033] of the Publication.

[04] In the Office action of 6/6/11:

[04a] Claim 6, which recited a "filament", is broad enough to include the elected species. It was not withdrawn. The arguments presented in the remarks of 9/1/11 do not challenge the propriety of the examination of claim 6.

[04b] Claim 9 was considered withdrawn as being directed to a non-elected species – specifically, a magnet. The arguments presented in the remarks of 9/1/11 do not challenge the propriety of the withdrawal of claim 9.

[05] In the newly added claims of 9/1/11:

[05a] Claims 42-43 refer to a "sensed environmental condition", which appears to be directed to the elected embodiment. As such, claims 42-43 will be examined.

[05b] Claim 45 refers to a fastener that is detachable in response to ultrasound waves. This fastener and the elected fastener are mutually exclusive. Therefore, claim 45 is considered withdrawn as being directed toward an unelected species.

Claim Rejections - 35 U.S.C. § 112 – Means Plus Function

[06] Claim(s) 1 and 31 (and all claims dependent thereon) invoke 35 U.S.C. 112, Sixth Paragraph, because:

[06a] the claim limitations use the phrase "means for" or "step for";

[06b] the "means for" or "step for" is modified by functional language; and

- [06c] the phrase "means for" or "step for" is not modified by sufficient structure, material, or acts for achieving the specified function.
- [07] This invocation applies to the "means for detaching the first part and the second part during the passage of said device through said gastrointestinal tract."
- [08] The specification does not disclose structure that corresponds to the recited "means for detaching the first part and the second part during the passage of said device through said gastrointestinal tract." The proper test for meeting the definiteness requirement is that the corresponding structure (or material or acts) of a means (or step)-plus-function limitation must be disclosed in the specification itself in a way that one skilled in the art will understand what structure (or material or acts) will perform the recited function. See *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 1381, 53 USPQ2d 1225, 1230 (Fed. Cir. 1999). See MPEP §2181(II).
- [09] Applicant has elected for prosecution a fastener comprising a degrading filament or glue. As noted on page 12 of the originally filed specification ([0033] of the Publication):

In still other embodiments, fastener 202 may be a degradable filament or glue that may degrade over the course of, for example, the several hours or other time period in which device 10 may be in a body before it reaches a designated body lumen such as for example the large intestine. In some embodiments such period may be from 6 to 8 hours. Such degradation may be precipitated by for example exposure to body temperatures, exposure to certain liquids, pH levels or other elements or conditions as may be present in a body lumen...

- [09b] Thus, Applicant clearly discloses that the fastener may degrade in predictable fashion upon exposure to various environmental conditions, thereby detaching the first part and the second part. But Applicant does not disclose the specific structure for causing the

detachment. Environmental conditions like body temperatures, certain liquids, and pH levels do not constitute structures that correspond to the recited "means for detaching."

- [10] Section 112, Paragraph Six permits the scope of a means plus function element to be determined by the corresponding structure and any equivalents thereof. If, as in this case, the corresponding structure is not identified in the specification, then the claim is indefinite.

Claim Rejections - 35 USC § 102

- [11] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- [12] The rejections of claim(s) 1-4,6,13,31-32,34,37 as being anticipated by Lewkowicz (2003/0018280) set forth in the Office action of 6/6/11 are withdrawn in view of the amendments of 9/1/11.

Response to Arguments

- [13] Applicant's arguments with regard to the prior art have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

- [14] Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
- [15] A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the

mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

- [16] Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip R Smith whose telephone number is (571) 272 6087 and whose email address is philip.smith@uspto.gov. The examiner can normally be reached between 9:00am and 5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen, can be reached on (571) 272 4963. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Philip R Smith/
Primary Examiner, Art Unit 3779